

Product group: Lactose
Brand name: SuperTab® 11 SD (NZ)
Product code: 747822
Product description: Lactose monohydrate
Document No.: PD-0084 Page 1 of 2

Manufacturing site: Fonterra Ltd., Kaponga, New Zealand
Product name: SuperTab® 11SD
Conforms to USP - NF, Ph.Eur., JP, Ch.P. Lactose monohydrate monograph, current at time of manufacture
Product description: A white or almost white, crystalline powder freely soluble in water, practically insoluble in ethanol
Residual solvents
(CPMP/ICH/283/95): No class 1,2,3 solvents are used during production

Physical-Chemical data:

Identification:
Appearance of solution (Ph.Eur.)
Clarity and Colour of Solution
Residue on ignition/Sulphated ash
Water (KF)
Loss on drying
Acidity
Specific Optical Rotation (on anhydrous basis)
Absorbance between 210-220 nm (1%, 1 cm)
Absorbance between 270-300 nm (1%, 1 cm)
Absorbance at 400 nm (10%, 1 cm)
Heavy metals
Arsenic
Assay by HPLC
Identify material by HPLC
Related substances by HPLC

Specification

Complies with Pharmacopoeia when tested
Clear and not more coloured than ref. BY 7
Clear and colourless or nearly colourless
max. 0.10 %
4.5 - 5.5 %
max. 1.0 %
max. 0.4 ml 0.1 N NaOH
+54.4° to +55.9°
max. 0.25
max. 0.07
max. 0.04
max. 5 ppm
max. 2 ppm
98.0 – 102.0 %
pass
pass

Microbiological data:

Total aerobic microbial count
Yeasts and moulds
E. coli
Salmonella

Specification

max. 100 cfu/g
max. 10 cfu/g
neg. in 10 g
neg. in 100 g

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Particle size (Sonic sifter)

% < 75 µm
% <150 µm
% <250 µm

Specification

max. 20
40 – 65
min. 90

Particle size distribution (Laser diffraction, dry)

D10
D50
D90

Specification

reported value
reported value
reported value

Storage:

Keep in original, unopened packing and away from strongly odorous materials.
Store at room temperature (normal warehouse conditions), allowing temporary excursions.

This document substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

Name : Dr. Bastiaan Dickhoff
Job title : Director Innovation & Technical Solutions

Signature : 

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The above facsimile signature is only for display.